



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/528,727

12/05/2005

Farid Vaghefi

26238A-US

4206

22225 7590 06/23/2009  
MARTIN SAVITZKY  
Law Offices of Martin Savitzky Esq.  
PO BOX 1027  
FORT WASHINGTON, PA 19034-1027

EXAMINER

ROYDS, LESLIE A

ART UNIT

PAPER NUMBER

1614

MAIL DATE

DELIVERY MODE

06/23/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<p align="center"><b>Advisory Action</b> <b>Before the Filing of an Appeal Brief</b></p>	<b>Application No.</b> 10/528,727	<b>Applicant(s)</b> VAGHEFI ET AL.	
	<b>Examiner</b> LESLIE A. ROYDS	<b>Art Unit</b> 1614	

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 11 June 2009 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.  
 b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

#### AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because  
 (a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);  
 (b) ☐ They raise the issue of new matter (see NOTE below);  
 (c) ☒ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
 (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).  
 5. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.  
 6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
 7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.  
 The status of the claim(s) is (or will be) as follows:  
 Claim(s) allowed: \_\_\_\_\_.  
 Claim(s) objected to: \_\_\_\_\_.  
 Claim(s) rejected: 1,4,5,7,9,11 and 24-26.  
 Claim(s) withdrawn from consideration: 12-23.

#### AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).  
 9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).  
 10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

#### REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:  
See Continuation Sheet.  
 12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). \_\_\_\_\_.  
 13. ☐ Other: \_\_\_\_\_.

/Ardin Marschel/  
Supervisory Patent Examiner, Art Unit 1614

/Leslie A. Royds/  
Patent Examiner, Art Unit 1614

Continuation of 3. NOTE: Applicant's proposed amending filed June 11, 2009 will not be entered into the record because the proposed amendment to claim 1 adds new limitations that have not been previously searched or considered and, therefore, the proposed claims would require further consideration and/or search.

For example, Applicant proposes amending claim 1 to now recite that the water-insoluble matrix material is both "elastic" and present "in an abuse-reducing amount". However, these are each properties of the water-insoluble matrix material that have not previously appeared in the instant claims (either original or amended) and, thus, are limitations that have not been previously searched or considered during the course of prosecution. In addition, the insertion of these limitations clearly narrows the scope of the claims and would also require further consideration and search beyond what has already been provided by the Office.

Accordingly, the proposed claim amendments will not be entered for the reasons above. Furthermore, the proposed claim amendments are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal because they clearly add new subject matter that has not been previously searched such that it would require both additional consideration and search.

Continuation of 11. does NOT place the application in condition for allowance because:

Applicant's request for reconsideration of the present application with regard to the rejections of record set forth in the final rejection dated April 14, 2009 in light of the amendments to the claims proposed and presented in the after-final amendment has been made. In light of the fact that the proposed amendments to the claims will not be entered into the record, Applicant's remarks directed to the obviation of these rejections as a result of the proposed amendments are not found persuasive.

In response to those remarks that Applicant has provided that would apply to the previously pending claim set, Applicant traverses the 112, first paragraph, rejection over the limitation "the dissolution rate of said active water soluble compound thereafter" by stating that the skilled artisan would clearly recognize that the only ingredient that is of dissolution interest is the active water soluble compound and directs the Examiner to Example 7 in support of his position.

This is unpersuasive. The disclosure at Ex.7 (para.[0100]) that Applicant relies on for support is directed to how the dissolution of the water-soluble active ingredient may be determined and is NOT directed to the actual alleged property of the composition, i.e., the dissolution rate of the composition per se. Accordingly, Applicant is again directed to his disclosure at p.6-7, which very clearly describes this dissolution property of increasing the aqueous dissolution of the active water-soluble compound by less than about 15% of the total pharmaceutically effective dosage amount in the first hour and "the dissolution rates of the preferred compositions are not substantially modified after the first hour of testing." The description of "the preferred compositions" clearly circumscribes the disclosed composition, which contains the active water-soluble compound and the coating material and the matrix, NOT the active water soluble compound alone. This rejection is maintained, despite Applicant's remarks to the contrary.

Secondly, Applicant traverses the instant 102 rejection, stating that the Examiner has not allegedly identified where Palermo et al. teach the composition of the present claims (i.e., an abuse-resistant composition that is capable of frustrating an abuser's crushing attempts to achieve the immediate release of the abusable compound). This is both unpersuasive and not a point well taken. The rejection very clearly identified the portions of Palermo et al. that teach the elements and structure instantly claimed. Applicant's attention is directed to the citations provided in the original rejection if he is in need of clarification. Moreover, Palermo et al. very clearly teaches that his disclosed composition is also abuse-resistant. The fact that the mechanism by which his invention is abuse-resistant is not the same as Applicant's is immaterial to the fact that Palermo et al. very clearly teaches the identical physical and structural components as that instantly claimed and, thus, whatever properties Applicant alleges are present in his composition must necessarily be present in the composition of the prior art because products of identical chemical composition cannot have mutually exclusive properties. Applicant is again directed to MPEP Sect. 2112.

Thirdly, and lastly, Applicant's remarks regarding crushing an OXYCONTIN tablet to result in rapid release have been considered, but are unpersuasive. Applicant again fails to make a comparison of the claimed product to the cited prior art of record to demonstrate that the instantly claimed product, in fact, has different properties from that of the prior art to Palermo et al. Since Palermo et al. discloses compositions that contain the same physical and structural elements to that of Applicant's claims, Applicant would need to provide some evidence or reasoning to support his position that the composition of PALERMO, which is the closest prior art of record, does not also contain these same properties that are allegedly in Applicant's product. The closest prior art product here is not simply an OXYCONTIN tablet that is commercially available, it is the prior art product of Palermo. Therefore, the rapid release of OXYCONTIN that may be achieved via crushing a commercial OXYCONTIN tablet clearly ignores both the teachings of Palermo and the fact that Palermo et al. very clearly provides for an abuse-resistant composition that inhibits the release of the opioid so as to avoid this property of rapid release that would be achieved via using an OXYCONTIN tablet without such an abuse-resistant mechanism. Accordingly, this proffered comparison of Applicant's abuse-resistant product to a non-abuse-resistant composition of an opioid is very clearly, and will remain, unpersuasive because (1) a non-abuse resistant OXYCONTIN tablet is NOT the closest prior art of record and (2) such a non-abuse-resistant composition would have been expected by the skilled artisan to result in rapid release of the opioid because it contains no compounds to inhibit such release, as are found in the invention of Palermo et al. The rejection is maintained.

For these reasons above, and those previously made of record in the final rejection dated April 14, 2009, of which said reasons are herein incorporated by reference, the claims remain rejected.

/Leslie A. Royds/  
Patent Examiner, Art Unit 1614